

REMARKS**Rejection and/or Objections of Claims and Traversal Thereof**

In the May 2, 2011 Final Office Action:

Claims 21, 23, 28, 30, 32 and 33 were objected to because of formalities;

Claims 21-24, 27, 28, 33 and 34 were rejected under 35 U.S.C. §102(b) as being anticipated by or in the alternative under 35 U.S.C. §103(a) over Tang, et al (WO 01/77169, hereinafter Tang); and

Claims 21-24, 27, 28 33 and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tang in view of Vernet et al (US Patent No. 6,653,448, hereinafter Vernet)

These rejections are hereby traversed and reconsideration of the patentability of the pending claims is therefore requested in light of the following remarks.

Claim 32

Claim 32 was objected to but there are no patentability rejections relating to the subject matter of the claim. Thus, once the formalities are addressed, the claimed subject matter should be found allowable. Applicants have included such recited subject matter into claim 21, thereby rendering claim 21 as allowable.

Claim Objections

Initially it should be noted that claim 30 was previously cancelled thus this claim should not be included in objected claims. Applicants have amended claims 21, 23, 28 and 32 according to the suggestions of the Office.

Rejection under 35 U.S.C. §102(b)/103(a)

1. Claims 21-24, 27, 28, 33 and 34 were rejected under 35 U.S.C. §102(b) as being anticipated by or in the alternative under 35 U.S.C. §103(a) over Tang. Applicants submit that this reference does not in any way anticipate or render obvious the presently claimed invention.

Applicants have amended claim 21 to recite the following:

21. A method of identifying a binding partner for a Futrin 2 polypeptide wherein the binding of the binding partner to the Futrin 2 polypeptide affects Wnt signaling activity of the Futrin 2 polypeptide, the method comprising:

- (a) providing a cellular system comprising the Futrin 2 polypeptide and contacting said Futrin 2 polypeptide with a compound to be screened; and
- (b) determining if binding of the compound to the Futrin 2 has occurred thereby to form a Futrin 2/ binding partner complex; and
- (c) assaying the Futrin 2/binding partner complex to determine if the Wnt signaling activity of the Futrin 2 polypeptide is altered by the binding of the binding partner and wherein the activity of Futrin 2 polypeptide is measured using a Wnt-inducible reporter assay.

The present invention recites a method of determining a binding partner that affects Wnt signaling activity of the Futrin 2 polypeptide and such activity is determined by using a Wnt-inducible reporter assay. It is evident that such an activity is not disclosed in the Tang reference.

The Office has the initial burden of establishing a *prima facie* case of anticipation by pointing out where all the claim limitations appear in a single reference. *In re Spada* 15 USPQ2d 1655 (Fed. Cir. 1990). Further, to anticipate a claim, a reference must be enabling. This point was reaffirmed in an April 7, 2000 decision of the Court of Appeals for the Federal Circuit (CAFC).¹ Citing *In re Paulsen*,² the court stated that to be anticipating, a prior art reference must:

- 1) disclose each and every limitation of the claimed invention;**
- 2) be enabling; and**
- 3) describe the claimed invention sufficiently to place it in possession of a person of ordinary skill in the field of the invention.**

Tang does not meet this standard. Tang describes methods for producing novel human stem cell growth factor-like polypeptides and antibodies for such polypeptides. The polynucleotides that encode such polypeptides are isolated from testis cells, human fetal skin, adult spleen and endothelial cells.

¹ *Helifix Ltd. v. Blok-Lok, Ltd.*, 54 USPQ2d 1299 (Fed. Cir. 2000).

² *In re Paulsen*, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994).

It is clear that the Tang reference is neither enabling nor describes the claimed invention sufficiently to place it in possession of a person of ordinary skill in the field of the invention. Where in this cited reference is there any discussion regarding the interaction between Futrin 2 polypeptide and such interaction affecting Wnt signaling activity? Clearly, there is none and the existence cannot be speculated on by the Office.

This Tang reference is approximately two hundred (200) pages including 48 different sequences and there is not a single section or portion of text in this entire reference, and the Office has not shown it, wherein there is a discussion of determining a binding partner for Futrin 2 polypeptide that would alter the interaction of the Futrin 2 polypeptide with Wnt thereby affecting the ability of the Futrin 2 polypeptide to alter the Wnt signaling activity. Importantly the present inventors ARE THE VERY FIRST to discover the relationship between Futrin 2 polypeptides and its Wnt signaling activity, thus it would be impossible that this Tang reference could anticipate the present invention.

Unfortunately, the Office has not provided any evidence on how a person of ordinary skill in the art would read the cited reference and make the huge leap of to include Futrin 2 polypeptide and interaction with Wnt from this reference because Futrin 2 is never mentioned once by Tang and the term “Wnt” was used exactly once relating to a “Wnt gene.” Applicants are amazed by the Office’s speculation that someone could go in the direction of applicants’ claimed invention without an undue amount of experimentation. *See In re Sheppard*, 144 USPQ 42, (CCPA 1981) (reversing a rejection under 35 U.S.C. Section 102(b) where the asserted prior art reference did not permit someone skilled in the art to possess the claimed invention). As such, this cited reference is not enabling and does not put the claimed invention in the hands of one skilled in the art. (*In re Sun*, 31 USPQ2d 1451 (Fed. Cir. 1993)).

There is certainly no anticipation because the disclosure in the reference is so broad that the likelihood of arriving at the presently claimed invention would be the same as discovering the combination of a safe by an inspection of its dials, *Ex parte Garvey*, 41 USPQ 583 (POBA 1939).

The comment by the Office that it inherently occurs is pure speculation and it is well settled in the law that to use the “inherency” rejection the event must occur each and every time. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *In re Oelrich*, 212 USPQ 323 (CCPA 1981).

Further, this Tang reference does not meet the requirements to establish a *prima facie* case of obviousness. Again, as stated above, the interaction of this Futrin 2 polypeptide with Wnt to affect the Wnt signaling activity is not described in the Tang reference and the Office has not provide such text.

The statement that it is inherently within the Tang reference is pure speculation. It is intuitive that something that is unknown could not possibly be obvious.

The Court's decision in *In re Spormann*, 150 USPQ 449 (CCPA 1966), bears directly on point:

“The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown”

Therefore, how could a skilled artisan make any modification while arriving at an invention that possesses the heretofore unknown characteristic. There is no disclosure in Tang to determine if a binding partner of Futrin 2 could alter the Wnt signaling activity. While it is possible that, serendipitously, the invention would have such a feature, serendipity is not a valid basis for asserting obviousness.

So the Office is really taking bits and pieces from Tang and extrapolating with the hope of somehow coming upon applicants' claimed invention even though Futrin 2 polypeptide and Wnt are **NEVER MENTIONED** in the Tang reference. Further, there is certainly no disclosure about the interaction of the Futrin 2 polypeptide with Wnt and the modification of the Wnt signaling activity by the Futrin 2 polypeptide.

Citing portions of *KSL* Court decision does not bolster the Office's arguments. Applicants believe that the Office is using the concept of “obvious to try” even though such terms have been avoided. Thus, it may be important for the Office to review the “*In re Kubin*” ruling decided on April 3, 2009 because it provides further guidance showing that the presently claimed invention is not obvious. (See *In re Kubin*, 90 USPQ2d 1417 (Fed. Cir. 2009). Specifically, the *Kubin* Court revisited the *In re O'Farrell* decision (*In re O'Farrell*, 853 F.2d 894(Fed Cir. 1988)) and discussed that to differentiate between proper and improper applications of “obvious to try,” the *O'Farrell* Court outlined two classes of situations where “obvious to try” is erroneously equated with obviousness under §103. In the first class of cases:

what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a

successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

Notably, the 48 sequences and almost 200 pages of text in the Tang reference which includes an extremely large number of possibilities would never be considered as a finite number of choices. Further there is not a single sentence or word in this Tang reference that even considers the interaction between Futrin 2 polypeptide and Wnt must less that Futrin 2 polypeptide has the ability to alter Wnt-signaling activity.

The second class of *O'Farrell's* impermissible “obvious to try” situations occurs where

what was “obvious to try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

There is no guidance in the cited reference to go in the direction of applicants’ claimed invention and certainly, no hope of success. Applicants insist that the Office is using impermissible hindsight which is unacceptable to establish a case of obviousness.

In light of the above discussion, applicants submit that the Office has not met its burden of establishing a *prima facie* case of obviousness. Accordingly, withdrawal of the rejection under obviousness is respectfully requested.

2. Claims 21-24, 27, 28 33 and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tang in view of Vernet. Applicants insist that the proposed combination does not establish a *prima facie* case of obviousness. Clearly the shortcomings of Tang are not rectified by Vernet.

Even if Vernet discloses the use of the luciferase reporter assay, this reference is only concerned with proteins that binding directly to the Wnt -7B like protein. There is nothing in this entire reference that discusses finding a binding partner that binds to Futrin 2 polypeptide wherein such binding alters the Futrin-2 polypeptide interaction with Wnt signaling cascade. One merely has to read the section of this Vernet patent cited by the Office (bottom of column 41 to top of 42) to understand that all testing is conducted to determine binding partners that directly bind with the Wnt 7B like protein.

Thus, the combination does not in any way teach or suggest the presently claimed invention and does not defeat the patentability of the presently claimed invention. Applicants request reconsideration and the withdrawal of all rejections under section 102(b) and/or section 103(a).

Petition for Extension and Fees Payable

Applicants request a three month extension and have included herewith a Request for Continued Examination. The fees for the extension and RCE are being paid herewith by electronic transfer. If any additional fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Marvich reconsider the patentability of the pending claims in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. If any issues remain outstanding incident to the allowance of the application, Examiner Marvich is requested to contact the undersigned attorney at (919) 286-8089.

Respectfully submitted,

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